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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ROBINSON, BINTA M

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 08/27/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant N .

09/485,292

Applicant(s)

KLAR ET AL.

Examiner

Binta M. Robinson

Art Unit

1625

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 13-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The examiner notes the applicant's election of species of example 1 disclosed on page 182 of the specification. This species will now be used as a reference point for the examiner to create a natural genus based on a liberal interpretation of the doctrine of legal and chemical equivalence and restriction will be required under 35 U. S. C. 121.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-30, drawn to the compound of formula I where D-E is CH₂-CH₂, X is CR₁₀R₁₁, where R₁₀ is 4-thiazolyl substituted with alkyl or 4-oxazole substituted with alkyl, R₁₁ is H, C₁-C₂₀ alkyl, R_{1a} and R_{1b} are independently H, C₁-C₁₀ alkyl, carbocyclic aryl, C₇-C₂₀ aralkyl, R₃ is H or C₁-C₁₀ alkyl, R_{4a} and R_{4b} is H, C₁-C₁₀ alkyl, or carbocyclic aryl, R₆ and R₇ taken together form a bond or are each H, R₈ is H, C₁-C₂₀ alkyl, carbocyclic aryl, C₇-C₂₀ carbocyclic aryl which can be optionally substituted with nonheterocyclic rings, Y is O and Z is O, the process of producing a compound of formula I as defined above, classified in class 548, subclass 204 and 217.
- II. Claims 1-30, drawn to the compound of formula I where D-E, X, R_{1a} and R_{1b}, R₃, R_{4a} and R_{4b}, R₆ and R₇ and Y and Z are all moieties not defined in group I, the process of producing a compound of formula I as defined above in group II and , classified in various classes and subclasses.

Art Unit: 1625

- III. Claims 13-26, drawn to a compound of formula A' drawn to the process for the producing of compounds of the formula A, classified in various classes and subclasses.
- IV. Claims 27-30, drawn to the process for the production of a compound of formula C, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

In the instant case the different inventions have achieved a separate status in the art, have separate fields that aren't coextensive, and are capable of supporting separate patents. Further, a prior art reference that would anticipate the claims under 35 USC 102(b) would not render obvious the same claim(s) under 35 U. S. C. 103 (a) with respect to another member. Searching the entire genus would be a burden on the USPTO in terms of time and expense.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The applicant's election of species falls into group I and group I will therefore be examined. If the applicant's elect to prosecute groups II-IV in further applications, these groups may be subject to further restriction requirement.

Claims 14-30 as well as the unelected portions of claims 1-13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim 11 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Change to 103
✓
Claim(s) 1-12 are rejected under 35 U.S.C. 102(a) as being anticipated by CA 132:293587r et. al. (See Reference U). CA 132 293587r discloses the instant compound, compound IV. At page 674, see the instant compound IV, oxacyclohexadec-13-ene-2,6-dione, 4,8-dihydroxy-5,5,7,9-tetramethyl-16-[(1E)-1-methyl-2-(2-methyl-4-thiazolyl)ethenyl]-, (4S, 7R, 8S, 9S, 13Z, 16S).

Change to 103
✓
Claim(s) 1-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Nicolaou et. al. (See Reference V). Nicolaou et. al. discloses the instant compound, compound oxacyclohexadec-13-ene-2,6-dione, 4-8-dihydroxy-5,5,7,9,13-pentamethyl-16-

Art Unit: 1625

[(1E)-1-methyl-2-(2-methyl-4-oxazolyl)ethenyl]-, (4S, 7R, 8S, 9S, 13Z, 16S). At pages 1971-1986, see the instant compound.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

100ef Claims 1-13 is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not provide enablement for R1a, R1b, R2a, R2b, R4a, R4b, R5, R8, R10, and R11 equal to all aryl, C7-C20 aralkyl groups which according to the specification can encompass heterocyclic groups. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte* Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

----- There are many factors to be considered when determining whether there -----
is sufficient evidence to support a determination that a disclosure does not satisfy
the enablement requirement and whether any necessary experimentation is

Art Unit: 1625

"undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the breadth of the claims, R1a, R1b, R2a, R2b, R4a, R4b, R5, R8, R10, R11 encompasses a much wider Markush grouping of radicals than those radicals synthesized. In terms of the second Wands factor, these products are useful as antitumour agents. In terms of the fifth Wands factor, the level of predictability in the art is low because the applicant does not test any of these compounds for their pharmaceutical effects. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not test any of these compounds for their pharmaceutical effects nor does the applicant synthesize compounds where R1a, R1b, R2a, R2b, R4a, R4b, R5, R8, R10, R11 encompass the full breadth of the aryl or aralkyl moieties claimed. In terms of the seventh Wands factor, the applicant does not provide any working examples. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Art Unit: 1625

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 1-13 in part are rejected under 35 U.S.C. 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

✓ A. In claims 1-7, 9 in part, the term "derivatives" is indefinite. The term "Derivatives" is not a statutory class of invention. Additionally, the term "derivatives" is plural rather than singular and it is unclear as to whether or not the applicant is claiming a composition or a compound. The phrase "A compound" is suggested.

✓ B. In claims 8, 11-12, the term "compounds" is indefinite. It is unclear as to whether or not the applicant is claiming a composition or a compound. The phrase "A compound" is suggested.

✓ C. In claims 1-12, the phrase "general formula" is indefinite. The term "formula" is suggested.

✓ D. In claim 10, the phrase "Pharmaceutical preparations" is indefinite because it is not a statutory class of invention. The phrase "A pharmaceutical composition" is suggested.

✓ E. Claim 11 provides for the use of the compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

✓ F. In claim 9, page 293, the phrase "characterized in that" is indefinite. The term "wherein" is suggested.

Art Unit: 1625

ref G. In claim 2-7, , the phrase "the remainder of the molecule is identical to naturally occurring epothilone A or B" is indefinite. It is unclear as to how the remainder of the molecule is identical to the naturally occurring epothilone A or B.

ref H. In claim 12, page 298, lines 23-24, the phrase "including all stereoisomers and mixtures thereof" is indefinite since it is unclear as to whether or not the applicant intends to claim the production of "a compound" or "a pharmaceutical composition."

The IDS filed 8/1/02 has been considered.

The references listed as X references on the international search report may read on the applicant's instant invention, but not on the examined, elected subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Alan L Rotman

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